



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/667,921

09/22/2003

Ioana M. RizoIU

BI9100CIPCON

9901

33197

7590

07/23/2008

STOUT, UXA, BUYAN & MULLINS LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

07/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,921	Applicant(s) RIZOIU ET AL.	
	Examiner david shay	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 6, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-48,52-59,65-69 and 76-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-48,52-59,65-69 and 76-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>June 6, 2008</u> . | 6) <input type="checkbox"/> Other: _____ |

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “imager, the imager being adapted to provide an image to the user of an area in proximity to the cannula distal end” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The amendment filed July 20, 2006 and August 8, 2007 are objected to under 35 U.S.C. 132(a) because they introduce new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the presumption and assertion that the priority of 60/064,465 is inherent despite its deletion from the continuing data.

Art Unit: 3735

Applicant has requested an explanation of the above rejection. The examiner notes that while the incorporation by reference may entitle applicant to the subject matter disclosed in provisional application 60/064,465, this does not provide priority based on this application. That is applicant cannot rely on the filing date of the provisional application, unless the requirements of 35 U.S.C. 120 are met. The requirements of 35 U.S.C. 120 are quite explicit:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

As applicants have deliberately chosen to remove the reference to provisional application 60/064,465 from the specification, the assertion of priority is new matter.

Applicants assert that no admission regarding the officially noticed facts set forth in the previous office action was made". However, applicants have made the admission by failing to seasonably challenge the examiner's official notice: "If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the

Art Unit: 3735

examiner's assertion of official notice or that the traverse was inadequate. See MPEP 2144.03 B and C.

With regard to the art rejections, applicant argues that the claims have been amended "to focus on intended use of the current invention and its associated structure" noting that the device is useful for tunneling through tissue. In particular applicant argues that the device does not need to have "a leading tip that is shaped to pierce, cut or disrupt the tissue" rather the laser "can do at least part, and in typical application substantially all of the cutting". However, a careful reading of Paolini et al reveals that this is also true of this device. For example, while claim 1 of Paolini et al recites that the skin is pierced, it is not until claim 4, dependent on claim 1, that recites that the piercing is done by the needle. Thus clearly Paolini et al envision the laser doing the vast majority of the cutting in such procedure. However, even if this were not the case, the instant claims are not so limited. The claims merely require that the end be "open", not that it be incapable of piercing etc. It is noted that the end of Paolini et al is "open" as required by the claims.

Next applicants assert that it was determined that the currently claimed device was designed "to have an interaction zone positioned off-axis to the central (longitudinal) axis of the cannula so that during tunneling through, for example, cartilage and hard tissue such as bone that cannula can be rotated about its axis to generate a tunnel sufficiently sized in width to allow the cannula to be advanced therethrough." However, no such "intended use" regarding rotation of the device is disclosed. Even if such an intended use were disclosed, it is not clear that this would lend patentability to the claimed structure, as there is no disclosed or argued advantage to such a configuration.

The examiner has taken official notice that of the obviousness of configuring devices for and using devices for the removal of fat in joints or the abdomen since these are known sites of fat tissue; to employ sterile fluids, since this prevents infection when operating on internal tissue; to construct the device from medical grade plastics, since this is a notorious material for medical devices; and to construct the device of stainless steel, since this is a notorious material for medical devices and is inert. Applicant has not challenged these determinations and they are now considered admitted prior art.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 39-46, 48, 52, 53, 65-68, 76, 77, 79, and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rizioiu et al (WO '928) in combination with Paolini et al, Messengill, and the admitted prior art of configuring devices for and using devices for the removal of fat in joints or the abdomen since these are known sites of fat tissue; to employ sterile fluids, since this prevents infection when operating on internal tissue; to construct the device from medical grade plastics, since this is a notorious material for medical devices; and to construct the device of stainless steel, since this is a notorious material for medical devices and is inert. Rizioiu et al (WO '928) teach a tissue removal device and method with hydrokinetic energy generated by the claimed lasers and using water, epinephrine and/or anesthetic as the fluid. Paolini et al teach having the zone wherein ablative energy used to act upon the tissue to be removed interacts therewith beyond the distal end of the cannula. Messangill teaches the removal of fat tissue using a cannula which delivers hydrokinetic energy to the tissue to be removed. It would have been obvious to the artisan or ordinary skill to employ the hydrokinetic energy generators and

Art Unit: 3735

steps and fluids of Rizoiu et al (WO '928) in the method and device of Massengill, since Massengill teaches no particular laser and since the claimed fluids are equivalent and or compatible with water when generating the hydrokinetic energy, as taught by Rizoiu et al (WO '928); or to employ the cannula delivery system and steps of Massengill in the device and method of Rizoiu et al (WO '928) , since Rizoiu et al (WO '928) teaches that the device and method can be used on many kinds of tissue and can include many different types of instruments; and in either case, to configure the device such that the interaction zone is beyond the end of the cannula as taught by Paolini et al, since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no unexpected result; to locate the axis of the electromagnetic energy transmitter closer to the wall of the cannula than the cannula axis, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would incrementally remove tissue, thus enabling a determination of the nature of (i.e. desirability for continued ablation thereof) the next layer of tissue before removal thereof, to configure the device for removal of fat tissue in joints or the abdomen since these are known sites of fat tissue, official notice of which has already been taken; to employ sterile fluids, since this prevents infection when operating on internal tissue, official notice of which has already been taken; to construct the device from medical grade plastics, since this is a notorious material for medical devices, official notice of which has already been taken; and to construct the device of stainless steel, since this is a notorious material for medical devices and is inert, official notice of which has already been taken, any disruptive forces will propagate in all directions and act on any tissue which is in the cannula, thus producing a device and method such as claimed.

Claims 47, 54-59, 69, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over RizoIU et al (WO '928) in combination with Paolini et al, Massengill, and the admitted prior art of configuring devices for and using devices for the removal of fat in joints or the abdomen since these are known sites of fat tissue; to employ sterile fluids, since this prevents infection when operating on internal tissue; to construct the device from medical grade plastics, since this is a notorious material for medical devices; and to construct the device of stainless steel, since this is a notorious material for medical devices and is inert as applied to claims 39-46, 48, 52, 53, 65-68, 76, 77, 79, and 80 above, and further in combination with Kittrell et al. Kittrell et al teach a tissue removal device with imaging capabilities. It would have been obvious to the artisan of ordinary skill to provide the infrared imaging device of Kittrell et al. in the device of RizoIU et al (WO '928) in combination with Paolini et al, Massengill since this would enable the surgeon to assure that the tissue is kept at a safe temperature, since this will minimize the damage to nerves and blood vessels, thus producing a device such as claimed.

Applicant's arguments filed April 18, 2008 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 76-80 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 3735

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/
Primary Examiner, Art Unit 3735